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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,764	09/30/2003	Hoa Duc Nguyen		6271

7590 09/25/2007
HIGH STANDARD PRODUCTS CORPORATION
SUITE 225
14441 BEACH BLVD.
WESTMINSTER, CA 92683

EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,764

Applicant(s)

NGUYEN ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) 30,32 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29,31,33-35 and 37-44 is/are rejected.
- 7) ☒ Claim(s) 41,42 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/30/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment and election of species filed on 07/13/07 are acknowledged. Claims 25-44 are pending in the application. Claims 30, 32 and 36 are withdrawn from consideration as directed toward non-elected species. Claims 25-29, 31, 33-35 and 37-44 are considered on merits.

Information Disclosure Statement

2. The information disclosure statement filed 09/30/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

3. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

At least one mass spectrum of the carboxylic acid ester and internal standard should be provided for illustrative purposes.

Claim Objections

4. Claims 41, 42 and 44 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 41 does not recite any active step and therefore does not further limit the subject matter of the parent claim. Regarding claim 43, all steps in parent claim 25 are obviously performed in the sequence recited in the claim, and therefore claim 43 does not further limit the subject matter of claim 25. Regarding claim 44,

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claim 25 recites specific reactions for the conversion step, which are quantitative, and therefore claim 44 does not further limit the subject matter of claim 44.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25-29, 31, 33-35 and 37-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method, in which a carboxylic acid ester internal standard is an ester of the carboxylic acid to be identified, does not reasonably provide enablement for the method, in which the internal standard has a different structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claim 25 recites that the carboxylic ester obtained from the carboxylic acid should be of an identical structure as that of the internal standard, which is possible only if the internal standard is the ester of the carboxylic acid to be identified. On the other hand, if the internal standard has a known structure, and the structure is the same as that of the ester of the carboxylic acid to be identified, it is not clear, why the carboxylic acid should be identified at all, since its structure is *a priori* known.

Claims 25-29, 31, 33-35, 37-40 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method, “wherein there is not conversion of the stable isotope labeled carboxylic acid ester internal standard to its corresponding non-labeled carboxylic acid ester compound during step b)”; as recited in claim 41, does not reasonably provide enablement for the method, for which such requirement is not fulfilled.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 25-29, 31, 33-35 and 37-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites converting the carboxylic acid in said sample into a "carboxylic acid ester of identical structure as that of said carboxylic acid ester internal standard except for the stable isotope atoms". First, it is not clear, why the carboxylic acid should be identified, if the internal standard is of the same structure as the ester of the carboxylic acids that is supposed to be identified? There is a contradiction in the subject matter of the claim, which renders claim 25 and all dependent claim unclear. Further, it is not clear, which "stable isotope atoms" are meant in the claim, and which compound they belong to - the internal standard, or the carboxylic acid? This uncertainty renders claims 25 and 27 unclear and indefinite.

It is not apparent, if for the plurality of carboxylic acids to be identified a plurality of internal standards with *a priori* known structures should be prepared. Also, if it would be possible to prepare a plurality of internal standard with known structures, it means that all carboxylic structures are known, and therefore it is not clear, what is the purpose of the method. Just quantifying of the known carboxylic acids? The subject matter of the pending claims should be clarified.

Claim 41 is not clear. Which conditions does it recite in order to fulfill the requirement of the recitation? The condition does not seem to be recited. Moreover, the requirement recited in claim 41 should be inherent for the method recited in the parent claim; otherwise, the method for quantification of the carboxylic acid recited in claim 25 becomes un-enabled.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 25-29, 31, 33-35 and 37-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Magera et al. (Clin. Chem., 2000) in view of Hušek (J. Chromat. B, 1998).

Magera discloses method of measuring methylmalonic acid (MMA) “in plasma and urine by stable-isotope dilution and electrospray tandem mass spectrometry” (Title), the method comprising adding internal standard MMA-d₃ to the sample, preparing butyl ester derivatives, extracting obtained esters of MMA and MMA-d₃ by solid-phase extraction and quantifying MMA in the sample by ESI-MS/MS.

Magera does not specifically teach adding internal standard in the form of ester or preparing butyl or other alkyl esters using chloroformate and corresponding alcohol.

Hušek indicates that chloroformates were revealed “as extraordinarily suitable esterification agents for transforming the carboxyl into the ester instantaneously” (using corresponding alcohols) (page 67).

It would have been obvious for any person of ordinary skill in the art to prepare esters disclosed by Magera using Hušek’s method, because Hušek specifically indicates that chloroformates are extraordinary suitable agents for transforming the carboxyl into the ester instantaneously. It would have been obvious for any person of ordinary skill in the art to first

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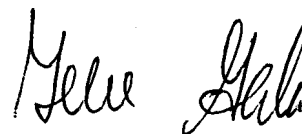
prepare isotopically labeled internal standards in the form of deuterated esters and add them to the sample comprising carboxylic acid(s), because the esters can be prepared by the same efficient esterification method that is taught by Hušek using relatively cheap deuterated alcohols.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/4/2007



**YELENA GAKH
PRIMARY EXAMINER**